Food and Drug Administration, HHS

(1) The ingredient is used as a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter and as a solvent and vehicle as defined in

 $\S170.3(0)(27)$ of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in \$170.3(n)(1) of this chapter; nonalcoholic beverages and beverage bases as defined in \$170.3(n)(3) of this chapter; chewing gum as defined in \$170.3(n)(6) of this chapter; and meat products as defined in \$170.3(n)(29) of this chapter.

(d) Prior sanctions for this ingredient different from the use established in this section do not exist or have been

waived.

[54 FR 7403 Feb. 21, 1989]

§ 184.1324 Glyceryl monostearate.

- Glyceryl monostearate, known as monostearin, is a mixture of variable proportions of glyceryl monostearate (C₂₁H₄₂O₄, CAS Reg. No. 31566-31-1),glyceryl monopalmitate (C₁₉H₃₈O₄, CAS Reg. No. 26657-96-5) and glyceryl esters of fatty acids present in commercial stearic acid. Glyceryl monostearate prepared is glycerolysis of certain fats or oils that are derived from edible sources or by esterification, with glycerin, of stearic acid that is derived from edible sources.
- (b) FDA is developing food-grade specifications for glyceryl monostearate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not not exist or have been waived.

[54 FR 7403 Feb. 21, 1989]

§184.1328 Glyceryl behenate.

(a) Glyceryl behenate is a mixture of glyceryl esters of behenic acid made from glycerin and behenic acid (a saturated C_{22} fatty acid). The mixture con-

tains predominately glyceryl dibehenate.

(b) The ingredient meets the following specifications:

- (1) 10 to 20 percent monoglyceride, 47 to 59 percent diglyceride, 26 to 38 percent triglyceride, and not more than 2.5 percent free fatty acids.

 (2) Behenic acid. Between 80 and 90
- (2) Behenic acid. Between 80 and 90 percent of the total fatty acid content.
- (3) Acid value. Not more than 4. (4) Saponification value. Between 145 and 165.
 - (5) Iodine number. Not more than 3.

(6) Heavy metals (as Pb). Not more

than 10 parts per million.

- (c) In accordance with §184.1(b)(1) of this chapter, the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient is generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:
- (1) The ingredient is used as a formulation aid, as defined in §170.3(o)(14) of this chapter.
- (2) The ingredient is used in excipient formulations for use in tablets at levels not to exceed good manufacturing practice.

[52 FR 42430, Nov. 5, 1987]

§ 184.1329 Glyceryl palmitostearate.

- (a) Glyceryl palmitostearate is a mixture of mono-, di-, and triglyceryl esters of palmitic and stearic acids made from glycerin, palmitic acid, and stearic acid.
- (b) The ingredient meets the following specifications:
- (1) The substance is a mixture of mono-, di-, and triglycerides of palmitic acid and stearic acid.

(2) Heavy metals (as lead): Not more

than 10 parts per million.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a formulation aid, as defined in §170.3(o)(14) of

this chapter.

§ 184.1330

(2) The ingredient is used in excipient formulations for use in tablets at levels not to exceed good manufacturing practice.

[60 FR 63621, Dec. 12, 1995]

§184.1330 Acacia (gum arabic).

(a) Acacia (gum arabic) is the dried gummy exudate from stems and branches of trees of various species of the genus Acacia, family Leguminosae.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 7, which is in-

corporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or to: http://www.archives.gov/ go federal_register/ code_of_federal_regulations/

ibr locations.html.

(c) The ingredient is used in food under the following conditions:

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Beverages and beverage bases, § 170.3(n)(3) of this chapter.	2.0	Emulsifier and emulsifier salt, §170.3(o)(8) of this chapter; flavoring agent and adjuvant, §170.3(o)(12) of this chapter; formulation aid, §170.3(o)(14) of this chapter; sta-
Chewing gum, § 170.3(n)(6) of this chapter	5.6	bilizer and thickener, § 170.3(o)(28) of this chapter. Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; humectant, § 170.3(o)(16) of this chapter; surface-finishing agent, § 170.3(o)(30) of this chapter.
Confections and frostings, $\S170.3(n)(9)$ of this chapter.	12.4	
Dairy product analogs, § 170.3(n)(10) of this chapter	1.3	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Fats and oils, § 170.3(n)(12) of this chapter	1.5	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Gelatins, puddings, and fillings, § 170.3(n)(22) of this chapter.	2.5	Emulsifier and emulsifier salt, §170.3(o)(8) of this chapter; formulation aid, §170.3(o)(14) of this chapter.; stabilizer and thickener, §170.3(o)(28) of this chapter.
Hard candy and cough drops, §170.3(n)(25) of this chapter.	46.5	Flavoring agent and adjuvant, § 170.3(o)(12) of this chapter; formulation aid, § 170.3(o)(14) of this chapter.
Nuts and nut products, § 170.3(n)(32) of this chapter	8.3	Formulation aid, §170.3(o)(14) of this chapter; surface-finishing agent, §170.3(o)(30) of this chapter.
Quiescently frozen confection products	6.0	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Snack foods, § 170.3(n)(37) of this chapter	4.0	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter.
Soft candy, §170.3(n)(38) of this chapter	85.0	Emulsifier and emulsifier salt, §170.3(o)(8) of this chapter; firming agent, §170.3(o)(10) of this chapter; flavoring agent and adjuvant, §170.3(o)(12) of this chapter; formulation aid, §170.3(o)(14) of this chapter, humectant, §170.3(o)(16) of this chapter; stabilizer and thickener, §170.3(o)(28) of this chapter; surface-finishing agent, §170.3(o)(30) of this chapter.
All other food categories	1.0	

- (d) [Reserved]
- (e) Prior sanctions for this ingredient different from the uses established in

this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1983; 53 FR 5766, Feb. 26, 1988]